

ROGER BOWERS, Individually and On
Behalf of All Others Similarly Situated,

 \mathbf{v}_i

Defendants.

Case No. 18-10086

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Plaintiff Roger Bowers (“Plaintiff”), individually and on behalf of all other persons similarly situated, by his undersigned attorneys, for his complaint against Defendants, alleges the following based upon personal knowledge as to himself and his own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through his attorneys, which included, among other things, a review of the Defendants’ public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission (“SEC”) filings, wire and press releases published by and regarding Tesaro, Inc. (“Tesaro” or the “Company”), analysts’ reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

1. This is a federal securities class action on behalf of a class consisting of all persons other than Defendants who purchased or otherwise acquired Tesaro securities between March 14, 2016 and January 12, 2018, both dates inclusive (the “Class Period”), seeking to recover damages caused by Defendants’ violations of the federal securities laws and to pursue

remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. Tesaro is an oncology-focused biopharmaceutical company that identifies, acquires, develops, and commercializes cancer therapeutics and oncology supportive care products in the United States.

3. Founded in 2010, the Company is based in Waltham, Massachusetts, and its securities trade on the NASDAQ Global Select (“NASDAQ”) under the ticker symbol “AFL.”

4. At all relevant times, Tesaro’s product portfolio has included Varubi (rolapitant), a neurokinin-1 (NK-1) receptor antagonist for the prevention of chemotherapy induced nausea and vomiting. In 2015, the U.S. Food and Drug Administration (“FDA”) approved an oral version of Varubi. On March 14, 2016, Tesaro announced the submission of a New Drug Application (“NDA”) for an intravenous formulation of Varubi to the FDA. On October 25, 2017, Tesaro announced the FDA’s approval of its intravenous version of Varubi.

5. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company’s business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) substantial undisclosed health risks, including anaphylaxis and anaphylactic shock, were associated with Tesaro’s intravenous formulation of Varubi; and (ii) as a result of the foregoing, Tesaro’s shares traded at artificially inflated prices during the Class Period, and class members suffered significant losses and damages.

6. On January 12, 2018, post-market, Tesaro announced that it had updated the U.S. labeling for the intravenous formulation of Varubi after receiving reports of “[a]naphylaxis,

anaphylactic shock and other serious hypersensitivity reactions . . . in the post-marketing setting, some requiring hospitalization.” The Company further stated that it “has issued a Dear Healthcare Professional (DHCP) letter.”

7. On this news, Tesaro’s share price fell \$4.07 or 5.85%, to close at \$65.52 on January 16, 2018.

8. As a result of Defendants’ wrongful acts and omissions, and the precipitous decline in the market value of the Company’s securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

9. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and Section 27 of the Exchange Act.

11. Venue is proper in this Judicial District pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1391(b) as Tesaro’s principal executive offices are located within this Judicial District.

12. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

PARTIES

13. Plaintiff, as set forth in the attached Certification, acquired Tesaro securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

14. Defendant Tesaro is incorporated in Delaware, with principal executive offices located at 1000 Winter Street, Suite 3300, Waltham, Massachusetts 02451. Tesaro's securities trade on the NASDAQ under the ticker symbol "TSRO."

15. Defendant Leon O. Moulder Jr. ("Moulder") co-founded and has served at all relevant times as the Company's Chief Executive Officer ("CEO") and Director.

16. Defendant Timothy R. Pearson ("Pearson") has served at all relevant times as the Company's Chief Financial Officer ("CFO") and Executive Vice President.

17. The Defendants referenced above in ¶¶ 15-16 are sometimes referred to herein as the "Individual Defendants."

18. The Individual Defendants possessed the power and authority to control the contents of Tesaro's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of the Company's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with the Company, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

SUBSTANTIVE ALLEGATIONS

Background

19. Tesaro is an oncology-focused biopharmaceutical company that identifies, acquires, develops, and commercializes cancer therapeutics and oncology supportive care products in the United States.

20. At all relevant times, Tesaro's product portfolio has included Varubi (rolapitant), NK-1 receptor antagonist for the prevention of chemotherapy induced nausea and vomiting. In 2015, the FDA approved an oral version of Varubi.

Materially False and Misleading Statements Issued During the Class Period

21. The Class Period begins on March 14, 2016, when Tesaro issued a press release entitled "Tesaro Submits New Drug Application for Intravenous Rolapitant to the U.S. Food and Drug Administration." The press release stated, in relevant part:

WALTHAM, Mass., March 14, 2016 (GLOBE NEWSWIRE) -- TESARO, Inc. (NASDAQ:TSRO), an oncology-focused biopharmaceutical company, today announced that it has submitted the New Drug Application (NDA) for an intravenous (IV) formulation of rolapitant to the U.S. Food and Drug Administration (FDA).

...

"TESARO is committed to advancing new therapeutic options for patients with cancer, and the NDA submission for IV rolapitant represents a significant milestone for the Company," said Mary Lynne Hedley, Ph.D., President and COO of TESARO. "By developing an intravenous formulation of rolapitant, our goal is to provide oncologists additional flexibility in their choice of antiemetic regimens."

The NDA for IV rolapitant is supported by data from a clinical program that enrolled more than 400 subjects and included a bioequivalence study and several other supportive non-clinical and clinical studies. TESARO anticipates a standard 12-month review timeline for the IV rolapitant NDA.

22. On May 6, 2016, Tesaro filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended March 31, 2016 (the "Q1 2016 10-Q"). For the quarter, Tesaro reported a net loss of \$90.77 million, or \$2.22 per diluted share, on revenue of \$307,000, compared to a net loss of \$48.51 million, or \$1.30 per diluted share, on zero revenue for the same period in the prior year.

23. In the Q1 2016 10-Q, Tesaro stated, in part:

A summary description of our current products and product candidates is as follows:

- *Rolapitant* is a potent and long-acting neurokinin-1, or NK-1, receptor antagonist for the prevention of chemotherapy induced nausea and vomiting, or CINV. The oral form of rolapitant, VARUBI, has been approved for commercialization in the United States, and we are also developing an intravenous, or IV, formulation of rolapitant. In March 2016, we submitted a new drug application, or NDA, for IV rolapitant to the FDA. We also submitted a Marketing Authorisation Application, or MAA, for oral rolapitant to the European Medicines Agency, or EMA, in March 2016.

24. The Q1 2016 10-Q contained signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by the Individual Defendants, stating that "[t]he information contained in the [Q1 2016 10-Q] fairly presents, in all material respects, the financial condition and results of operations of the Company."

25. On August 5, 2016, Tesaro filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended June 30, 2016 (the "Q2 2016 10-Q"). For the quarter, Tesaro reported a net loss of \$58.41 million, or \$1.28 per diluted share, on revenue of \$36.56 million, compared to a net loss of \$60.56 million, or \$1.51 per diluted share, on zero revenue for the same period in the prior year.

26. In the Q2 2016 10-Q, Tesaro stated, in part:

A summary description of our current products and product candidates is as follows:

- *Rolapitant* is a potent and long-acting neurokinin-1, or NK-1, receptor antagonist for the prevention of chemotherapy induced nausea and vomiting, or CINV. The oral form of rolapitant, VARUBI, has been approved for commercialization in the United States, and we are also developing an intravenous, or IV, formulation of rolapitant. In March 2016, we submitted a new drug application, or NDA, for IV rolapitant to the FDA which was accepted for review in May 2016, with a target Prescription Drug User Fee Act, or PDUFA, date of January 11, 2017. We also submitted a Marketing Authorisation Application, or MAA, for oral rolapitant to the European Medicines Agency, or EMA, in March 2016, which the EMA has validated.

27. The Q2 2016 10-Q contained signed certifications pursuant to SOX by the Individual Defendants, stating that “[t]he information contained in the [Q2 2016 10-Q] fairly presents, in all material respects, the financial condition and results of operations of the Company.”

28. On November 4, 2016, Tesaro filed a quarterly report on Form 10-Q with the SEC, reporting the Company’s financial and operating results for the quarter ended September 30, 2016 (the “Q3 2016 10-Q”). For the quarter, Tesaro reported a net loss of \$101.15 million, or \$1.98 per diluted share, on revenue of \$3.73 million, compared to a net loss of \$66.59 million, or \$1.66 per diluted share, on revenue of \$87,000 for the same period in the prior year.

29. In the Q3 2016 10-Q, Tesaro stated, in part:

On September 1, 2015, the Company’s first commercial product, VARUBI® (rolapitant), was approved by the United States Food and Drug Administration, or FDA, in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. The Company commenced sales of VARUBI during the fourth quarter of 2015. In March 2016, the Company submitted a new drug application, or NDA, for intravenous rolapitant to the FDA which was accepted for review in May 2016, with a target Prescription Drug User Fee Act, or PDUFA, date of January 11, 2017. The Company also submitted a Marketing Authorization Application, or MAA, for oral rolapitant to the European Medicines Agency, or EMA, in March 2016, which the EMA has accepted for review.

...

A summary description of our current products and product candidates is as follows:

- *Rolapitant* is a potent and long-acting neurokinin-1, or NK-1, receptor antagonist for the prevention of chemotherapy induced nausea and vomiting, or CINV. The oral form of rolapitant, VARUBI, has been approved for commercialization in the United States, and we are also developing an intravenous, or IV, formulation of rolapitant. In March 2016, we submitted a new drug application, or NDA, for IV rolapitant to the FDA which was accepted for review in May 2016, with a target Prescription Drug User Fee Act, or PDUFA, date of January 11, 2017. We also submitted a Marketing Authorization Application, or MAA, for oral rolapitant to the European Medicines Agency, or EMA, in March 2016, which the EMA has accepted for review.

30. The Q3 2016 10-Q contained signed certifications pursuant to SOX by the Individual Defendants, stating that “[t]he information contained in the [Q3 2016 10-Q] fairly presents, in all material respects, the financial condition and results of operations of the Company.”

31. On February 28, 2017, Tesaro filed an annual report on Form 10-K with the SEC, reporting the Company’s financial and operating results for the quarter and year ended December 31, 2016 (the “2016 10-K”). For the quarter, Tesaro reported a net loss of \$136.94 million, or \$2.60 per diluted share, on revenue of \$4.23 million, compared to a net loss of \$75.76 million, or \$1.89 per diluted share, on revenue of \$230 million for the same period in the prior year. For 2016, Tesaro reported a net loss of \$387.47 million, or \$8.13 per diluted share, on revenue of \$44.82 million, compared to a net loss of \$251.41 million, or \$6.38 per diluted share, on revenue of \$317,000 for 2015.

32. In the 2016 10-K, Tesaro stated, in part:

A summary description of our current products and product candidates is as follows:

- *Rolapitant* is a potent and long-acting neurokinin-1, or NK-1, receptor antagonist for the prevention of chemotherapy induced nausea and vomiting,

or CINV. The oral form of rolapitant, VARUBI, is approved for commercialization in the United States, and we are developing an IV formulation of rolapitant. We submitted a new drug application, or NDA, for rolapitant IV to the FDA in March 2016. In January 2017, the FDA issued a Complete Response Letter requesting additional information regarding the in vitro release method utilized to characterize the drug product and demonstrate comparability of drug product produced by our two proposed commercial manufacturers of rolapitant IV that were included in the NDA. We will need to provide the additional requested information to the FDA in the form of a resubmission of the NDA, which the FDA will need to deem acceptable, in order for the NDA to be approved and for us to be allowed to market and sell rolapitant IV in the U.S. We also submitted a Marketing Authorization Application, or MAA, for oral rolapitant to the European Medicines Agency, or EMA, in March 2016. In February 2017, the EMA's Committee for Medicinal Products for Human Use, or CHMP, rendered a positive opinion for our MAA for oral rolapitant, for the prevention of delayed nausea and vomiting associated with highly and moderately emetogenic chemotherapy in adults.

Our Strategy

Our strategy is to leverage the experience and competencies of our management team to identify, acquire and develop promising drug candidates and to commercialize cancer therapeutics that are potentially safer and more effective than existing treatments.

The key components of our strategy are:

...

- ***Successfully Commercialize Rolapitant for the Prevention of CINV.*** On September 1, 2015, our first commercial product, VARUBI, was approved by the FDA, for use in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy. We launched VARUBI in November 2015. Our rolapitant program also includes the development of an IV formulation, for which we submitted an NDA to the FDA in March 2016. We also submitted an MAA for oral rolapitant to the EMA in March 2016. Pending regulatory approvals, we intend to launch rolapitant IV in the U.S., and oral rolapitant in Europe, in the second half of 2017. We intend to establish rolapitant as part of the standard of care for the prevention of CINV in patients who, consistent with established treatment guidelines, could benefit from an NK-1 receptor antagonist, in addition to treatment with a 5-HT3 receptor antagonist plus a corticosteroid.

33. The 2016 10-K contained signed certifications pursuant to SOX by the Individual Defendants, stating that “[t]he information contained in the [2016 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company.”

34. On May 9, 2017, Tesaro filed a quarterly report on Form 10-Q with the SEC, reporting the Company’s financial and operating results for the quarter ended March 31, 2017 (the “Q1 2017 10-Q”). For the quarter, Tesaro reported a net loss of \$136.73 million, or \$2.55 per diluted share, on revenue of \$3.07 million, compared to a net loss of \$90.98 million, or \$2.22 per diluted share, on revenue of \$300,000 for the same period in the prior year (as revised).

35. In the Q1 2017 10-Q, Tesaro stated, in part:

A summary description of our current products and product candidates is as follows:

- *Rolapitant* is a potent and long-acting neurokinin-1, or NK-1, receptor antagonist for the prevention of chemotherapy induced nausea and vomiting, or CINV. The oral form of rolapitant, VARUBI, is approved in the United States for use in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. The European Commission also approved oral rolapitant for the prevention of delayed nausea and vomiting associated with highly and moderately emetogenic chemotherapy in adults in April 2017. We will market rolapitant in the European Union under the brand name VARUBY®. We are also developing an intravenous, or IV, formulation of rolapitant. We submitted a new drug application, or NDA, for rolapitant IV to the United States Food and Drug Administration, or FDA, in March 2016. In January 2017, the FDA issued a Complete Response Letter requesting additional information regarding the in vitro release method utilized to characterize the drug product and demonstrate comparability of drug product produced by our two proposed commercial manufacturers of rolapitant IV that were included in the NDA. We resubmitted the NDA with such information to the FDA in April 2017, and the FDA will need to review and approve the resubmitted NDA in order for us to be allowed to market and sell rolapitant IV in the U.S.

36. The Q1 2017 10-Q contained signed certifications pursuant to SOX by the Individual Defendants, stating that “[t]he information contained in the [Q1 2017 10-Q] fairly

presents, in all material respects, the financial condition and results of operations of the Company.”

37. On August 8, 2017, Tesaro filed a quarterly report on Form 10-Q with the SEC, reporting the Company’s financial and operating results for the quarter ended June 30, 2017 (the “Q2 2017 10-Q”). For the quarter, Tesaro reported a net loss of \$152.06 million, or \$2.82 per diluted share, on revenue of \$29.46 million, compared to a net loss of \$59.15 million, or \$1.29 per diluted share, on revenue of \$35.81 million for the same period in the prior year (as revised).

38. In the Q2 2017 10-Q, Tesaro stated, in part:

A summary description of our current products and product candidates is as follows:

- *Rolapitant* is a potent and long-acting neurokinin-1, or NK-1, receptor antagonist for the prevention of chemotherapy induced nausea and vomiting, or CINV. The oral form of rolapitant, VARUBI, is approved in the United States for use in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. The European Commission also approved oral rolapitant for the prevention of delayed nausea and vomiting associated with highly and moderately emetogenic chemotherapy in adults in April 2017. We market rolapitant in the European Union under the brand name VARUBY®, and commenced sales of VARUBY in May 2017 on a country-by-country basis. We are also developing an intravenous, or IV, formulation of rolapitant. We submitted a new drug application, or NDA, for rolapitant IV to the United States Food and Drug Administration, or FDA, in March 2016. In January 2017, the FDA issued a Complete Response Letter requesting additional information regarding the in vitro release method utilized to characterize the drug product and demonstrate comparability of drug product produced by our two proposed commercial manufacturers of rolapitant IV that were included in the NDA. We resubmitted the NDA with such information to the FDA in April 2017, and the FDA will need to review and approve the resubmitted NDA in order for us to be allowed to market and sell rolapitant IV in the U.S. The target Prescription Drug User Fee Act action date is October 25, 2017.

39. The Q2 2017 10-Q contained signed certifications pursuant to SOX by the Individual Defendants, stating that “[t]he information contained in the [Q2 2017 10-Q] fairly

presents, in all material respects, the financial condition and results of operations of the Company.”

40. On October 25, 2017, Tesaro issued a press release entitled “Tesaro Announces U.S. FDA Approval of Varubi® IV for Delayed Nausea and Vomiting Associated With Cancer Chemotherapy.” In the press release, Tesaro stated, in relevant part:

WALTHAM, Mass., Oct. 25, 2017 (GLOBE NEWSWIRE) -- TESARO, Inc. (NASDAQ:TSRO), an oncology-focused biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has approved VARUBI® (rolapitant) IV in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. Delayed nausea and vomiting can occur anytime between 25 and 120 hours following chemotherapy, and is often extremely debilitating.

VARUBI is a highly selective and competitive antagonist of human substance P/neurokinin 1 (NK-1) receptors, which play an important role in the delayed phase of chemotherapy-induced nausea and vomiting (CINV). With a long plasma half-life of approximately seven days, a single dose of VARUBI, as part of an antiemetic regimen, significantly improved complete response (CR) rates in the delayed phase of CINV. Results from three Phase 3 trials of VARUBI oral tablets demonstrated a significant reduction in episodes of vomiting or use of rescue medication during the 25- to 120-hour period following administration of highly emetogenic and moderately emetogenic chemotherapy regimens. In addition, patients who received VARUBI reported experiencing less nausea that interfered with normal daily life and fewer episodes of vomiting or retching over multiple cycles of chemotherapy. Results from a bioequivalence trial demonstrated comparability of the IV and oral formulations of VARUBI.

...

“The approval of VARUBI IV represents a significant milestone for TESARO. The majority of NK-1 receptor antagonist doses are administered intravenously in the U.S., and with the introduction of VARUBI IV, we now offer healthcare providers a unique, easy-to-use option that fits well into standard operating practices of a chemotherapy clinic or hospital,” said Mary Lynne Hedley, Ph.D., President and COO of TESARO. “We will continue our efforts to expand awareness of delayed chemotherapy-induced nausea and vomiting, and plan to make this important medicine available next month.”

“Many healthcare providers tend to believe that CINV is no longer an unmet need but the reality is that more than half of patients treated with emetogenic chemotherapy experience delayed CINV, even when prescribed standard preventative therapies, such as a 5-HT3 receptor antagonist and dexamethasone,” said Lee Schwartzberg, M.D., Professor of Medicine at University of Tennessee Health Science Center. “The FDA approval of VARUBI IV gives doctors and nurses a new option to help protect their patients from these often preventable side effects.”

41. On November 7, 2017, Tesaro filed a quarterly report on Form 10-Q with the SEC, reporting the Company’s financial and operating results for the quarter ended September 30, 2017 (the “Q3 2017 10-Q”). For the quarter, Tesaro reported a net loss of \$25.28 million, or \$0.47 per diluted share, on revenue of \$142.77 million, compared to a net loss of \$87.85 million, or \$1.72 per diluted share, on revenue of \$16.99 million for the same period in the prior year (as revised).

42. In the Q3 2017 10-Q, Tesaro stated, in part:

A summary description of our current products and product candidates is as follows:

- *Rolapitant* is a potent and long-acting neurokinin-1, or NK-1, receptor antagonist for the prevention of chemotherapy induced nausea and vomiting, or CINV. The oral form of rolapitant, VARUBI, is approved in the United States for use in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. In October 2017, the United States Food and Drug Administration, or FDA, approved our new drug application, or NDA, for the intravenous, or IV, formulation of rolapitant. We expect to commence sales of VARUBI IV in the U.S. in the fourth quarter of 2017. The European Commission also approved oral rolapitant for the prevention of delayed nausea and vomiting associated with highly and moderately emetogenic chemotherapy in adults in April 2017. We market rolapitant in the European Union under the brand name VARUBY®, and commenced sales of VARUBY in May 2017 on a country-by-country basis.

43. The Q3 2017 10-Q contained signed certifications pursuant to SOX by the Individual Defendants, stating that “[t]he information contained in the [Q3 2017 10-Q] fairly

presents, in all material respects, the financial condition and results of operations of the Company.”

44. The statements referenced in ¶¶ 21-43 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company’s business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) substantial undisclosed health risks, including anaphylaxis and anaphylactic shock, were associated with Tesaro’s intravenous formulation of Varubi; and (ii) as a result of the foregoing, Tesaro’s shares traded at artificially inflated prices during the Class Period, and class members suffered significant losses and damages.

The Truth Begins to Emerge

45. On January 12, 2018, post-market, Tesaro issued a press release entitled “Tesaro Announces Updates to the U.S. Prescribing Information for Varubi® (rolapitant) Injectable Emulsion.” The press release stated, in relevant part:

WALTHAM, Mass., Jan. 12, 2018 (GLOBE NEWSWIRE) -- TESARO, Inc. (NASDAQ:TSRO), an oncology-focused biopharmaceutical company, today announced that it has updated the VARUBI® (rolapitant) injectable emulsion package insert in collaboration with the U.S. Food and Drug Administration (FDA). VARUBI injectable emulsion is a substance P/neurokinin (NK-1) receptor antagonist indicated for the prevention of delayed nausea and vomiting associated with chemotherapy in adults. The changes to the labeling include modifications to the CONTRAINDICATIONS, WARNINGS and PRECAUTIONS, and ADVERSE REACTIONS sections.

Following its introduction in late November 2017, TESARO estimates that at least 7,000 doses of VARUBI injectable emulsion have been administered to patients receiving emetogenic chemotherapy in the United States. ***Anaphylaxis, anaphylactic shock and other serious hypersensitivity reactions have been reported in the postmarketing setting, some requiring hospitalization.*** These reactions have occurred during or soon after the infusion of VARUBI injectable emulsion. Most reactions have occurred within the first few minutes of administration.

Patient safety is a paramount priority for TESARO. *In its commitment to ensuring patients and healthcare professionals are aware of the label update, TESARO has issued a Dear Healthcare Professional (DHCP) letter.* This letter, as well as the updated full prescribing information, has been posted on the VARUBI website (www.varubirx.com). Additionally, members of the TESARO field force will be calling on healthcare professionals to communicate this important new safety information.

Healthcare providers and patients are encouraged to report adverse events in patients taking VARUBI injectable emulsion to TESARO at 1-844-4-TESARO (1-844-483-7276). TESARO's medical information department may be reached at 1-844-4-TESARO (1-844-483-7276) to address any questions from healthcare providers about the information contained in this release, or the safe and effective use of VARUBI injectable emulsion.

(Emphases added.)

46. On this news, Tesaro's share price fell \$4.07 or 5.85%, to close at \$65.52 on January 16, 2018.

47. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

48. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Tesaro securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

49. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Tesaro securities were actively traded on the

NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Tesaro or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

50. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

51. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

52. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Tesaro;
- whether the Individual Defendants caused Tesaro to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Tesaro securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

53. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

54. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Tesaro securities are traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased, acquired and/or sold Tesaro securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

55. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

56. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State*

of *Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

57. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

58. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

59. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Tesaro securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Tesaro securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

60. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Tesaro securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Tesaro's finances and business prospects.

61. By virtue of their positions at Tesaro, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

62. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Tesaro, the Individual Defendants had knowledge of the details of Tesaro's internal affairs.

63. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of

Tesaro. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Tesaro's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Tesaro securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Tesaro's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Tesaro securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

64. During the Class Period, Tesaro securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Tesaro securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Tesaro securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Tesaro securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

65. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

66. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against The Individual Defendants)

67. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

68. During the Class Period, the Individual Defendants participated in the operation and management of Tesaro, and conducted and participated, directly and indirectly, in the conduct of Tesaro's business affairs. Because of their senior positions, they knew the adverse non-public information about Tesaro's misstatement of income and expenses and false financial statements.

69. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Tesaro's financial condition and results of operations, and to correct promptly any public statements issued by Tesaro which had become materially false or misleading.

70. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press

releases and public filings which Tesaro disseminated in the marketplace during the Class Period concerning Tesaro's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Tesaro to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of Tesaro within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Tesaro securities.

71. Each of the Individual Defendants, therefore, acted as a controlling person of Tesaro. By reason of their senior management positions and/or being directors of Tesaro, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Tesaro to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Tesaro and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

72. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Tesaro.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: January 17, 2018

Respectfully submitted,

ANDREWS DEVALERIO LLP

/s/ Daryl Andrews

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Daryl Andrews (BBO #658523)

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Attorneys for Plaintiff

Submission Date

2018-01-17 08:41:41

CERTIFICATION PURSUANT TO FEDERAL SECURITIES LAWS

1. I make this declaration pursuant to Section 27(a)(2) of the Securities Act of 1933 ("Securities Act") and/or Section 21D(a)(2) of the Securities Exchange Act of 1934 ("Exchange Act") as amended by the Private Securities Litigation Reform Act of 1995.
2. I have reviewed a Complaint against against Tesaro, Inc. ("Tesaro" or the "Company"), as well as media and analyst reports about the Company. Plaintiff believes and authorizes the filing of a comparable complaint on my behalf.
3. I did not purchase or acquire Tesaro securities at the direction of plaintiffs' counsel or in order to participate in any private action arising under the Securities Act or Exchange Act.
4. I am willing to serve as a representative party on behalf of a Class of investors who purchased or acquired Tesaro securities during the class period, including providing testimony at deposition and trial, if necessary. I understand that the Court has the authority to select the most adequate lead plaintiff in this action.
5. To the best of my current knowledge, the attached sheet lists all of my transactions in Tesaro securities during the Class Period as specified in the Complaint.
6. During the three-year period preceding the date on which this Certification is signed, I have not sought to serve as a representative party on behalf of a class under the federal securities laws.
7. I agree not to accept any payment for serving as a representative party on behalf of the class as set forth in the Complaint, beyond my pro rata share of any recovery, except such reasonable costs and expenses directly relating to the representation of the class as ordered or approved by the Court.
8. I declare under penalty of perjury that the foregoing is true and correct.

Name

Print Name

Roger Bowers

Acquisitions

Configurable list (if none enter none)

(see attached)

Sales

Documents & Message

(redacted)



Signature

Roger Bowers

Full Name

Roger Bowers

(redacted)



TESARO, INC. (TSRO)

Bowers, Roger

LIST OF PURCHASES AND SALES

DATE	PURCHASE OR SALE	NUMBER OF SHARES/UNITS	PRICE PER SHARES/UNITS
10/3/2017	Purchase	50	\$125.0000